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ANALYSIS OF OBSERVATION REPORTS OF CLINIC USE OF SULFAMETHOXINU--ETC (U)
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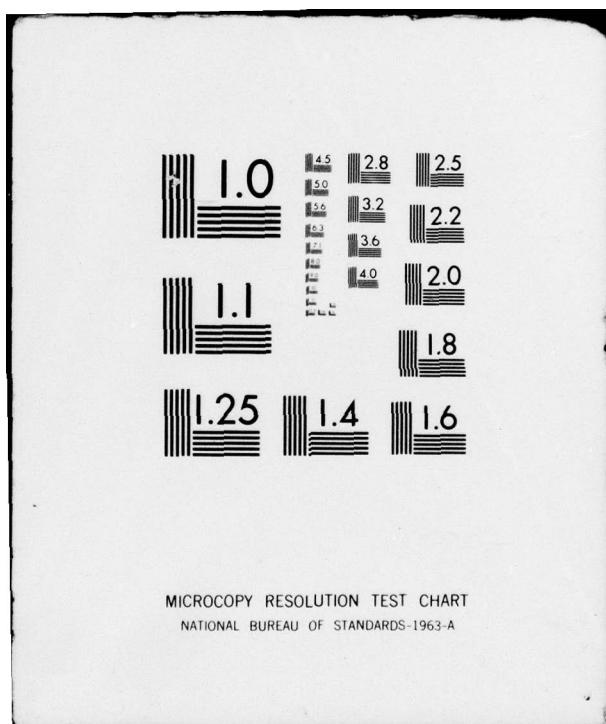
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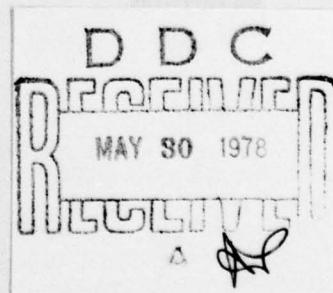
FOREIGN TECHNOLOGY DIVISION



ANALYSIS OF OBSERVATION REPORTS
OF CLINIC USE OF SULFAMETHOXINUM

by

Lu Hsiang-hua



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Analysis of Observation Reports
of Clinic Use of Sulfamethoxinum

Collaboration Team From Sian, Nanchang, Shanghai and
Tai-yuan For Testing Clinic Use of Sulfamethoxinum*

For the purpose of testing the effectiveness of sulfamethoxinum (SDM), more than twenty medical units and medicine testing units from four different places have collaboratively treated 389 cases of bacterial infection, and have proved that the half-life period of sulfamethoxinum in blood is 7.6-9.5 days and that sulfamethoxinum is an effective medicine by measuring the medicine density in blood of 135 persons. An analysis of the reports presented at a conference held in Tai-yuan in August, 1974 is to be made as follows.

Cases Selection and Methods of Using the Medicine

The general condition of treating each case in four places is that before taking this medicine, the patient did not have any treatment by using antibacteria medicine or had treatment without result. None of the patients has history of sulfa-allergy, or evidence of damage of the function of liver or kidney because of bacterial infection. They are all adults and their cases are mainly in the area of general medicine; infectious diseases; diseases of ears, eyes, mouth and throat; and surgery. They are ^{asked} to stay in hospital for treatment and observation, and only 23 of them are treated in village clinics.

The medicine used in these case-treatments is sulfamethoxinum manufactured in Tai-yuan, and the brand number of this medicine is 720812. The

*

The responsible unit: Office of Medicine Standardization, Shansi Province

methods of using this medicine can be classified into three groups: (1) first dose is 1.5g., then once a week and each dose is 0.5g. (referred hereafter as group of initial dose 1.5g.); (2) first dose is 1.0g., then once a week and each dose is 0.5g. (referred hereafter as group of initial dose 1.0g.); and (3) first dose is 1.0g., then twice a week and each dose is 0.5g. (referred hereafter as group of twice a week).

The duration of treatment is determined by the seriousness of the case. Generally it takes 1-2 weeks, and the longest one is 4 weeks. During the period of taking this medicine, the patients are not allowed to take any other additional antibacterial medicine.

Analysis of Treatment Effectiveness

Of the 389 cases of 21 different kinds of bacterial infectious diseases, the cured rate is 69.4% and the effectiveness rate is 88.9%. Among these cases, of 67 upper respiratory organ infection and 97 acute tonsillitis, the cured rate is 95.5% and 89.7% respectively, and of 83 acute bacterial dysentery and 23 pneumonia, the cured rate is 78.3% and 73.9% respectively. The total result can be seen in Table 1.

The treatment effectiveness to the following few main adaptational cases...

1. Acute Tonsillitis: Generally after taking the medicine once or twice, the patient's temperature goes down, sore throat disappears and the tonsilla swelling is subdued. Most cases are cured in 3-5 days. There is only one case of acute tonsillitis lacunaris, the patient, before coming to the hospital, had 20 penicillin shots and took tetracycline and some kind of

Table 1 Treatment Effectiveness of Sulfamethoxinum to 20 Different Kinds of Bacterial Diseases

Name of Disease	Number of Cases					Percentage (%)				
	I	II	III	IV	V	I	II	III	IV	V
1. 急性扁桃体炎	87	5	3	2	97	89.7	5.2	3.1	2.1	100.0
2. 上呼吸道感染	64	...	1	2	67	95.5	...	1.5	3.0	100.0
3. 急性支气管炎	7	1	2	...	10	70.0	10.0	20.0	...	100.0
4. 肺炎	17	3	1	2	23	73.9	13.0	4.3	8.7	100.0
5. 慢性支气管炎及合并感染	6	3	18	4	31	19.4	9.7	58.1	12.9	100.0
6. 支气管哮喘合并感染	1	...	1	5	7	14.3	...	14.3	71.4	100.0
7. 急性菌痢	65	4	10	4	83	78.3	4.8	12.0	4.8	100.0
8. 泌尿系感染 [△]	3	4	3	11	21	14.3	19.0	14.3	52.4	100.0
9. 慢性胆道感染	1	1	1	1	4	25.0	25.0	25.0	25.0	100.0
10. 软组织感染*	14	4	1	3	22	63.6	18.2	4.5	13.6	100.0
11. 急性淋巴结炎	...	1	2	2	5	...	20.0	40.0	40.0	100.0
12. 心脏病合并肺部感染	...	1	2	4	7	...	14.3	28.6	57.1	100.0
13. 其他**	5	1	3	3	12	41.7	8.3	25.0	25.0	100.0
Total	270	28	48	43	389	69.4	7.2	12.3	11.1	100.0

.....
Translator's note 1:

1. Acute Tonsillitis
2. Upper Respiratory Organ Infection
3. Acute Bronchitis
4. Pneumonia
5. Chronic Bronchitis and Combined Infection
6. Combination of Bronchophony and Infection
7. Acute Bacterial Dysentery
8. Uropoietic System Infection
9. Chronic Bile-Duct Infection
10. Soft Structure Infection
11. Acute Lymphnoditis
12. Combination of Heart Disease and Lung Infection
13. Others

Note 2:

I. Cured; II. Very effective; III. Becoming better; IV. Ineffective and V. Total.

△ Uropoietic system infection including: nephropyelitis and acute cystitis and chronic cystitis with acute relapse.

* Soft structure infection including: pustula, carbuncle, erysipelas, dermatocellulitis, mastitis, general skin infection and abscess.

** Others including: ineffective in two cases of bronchiectasis combined with infection; cured in two cases of acute lymphangitis; cured in one case of acute laryngitis; cured in one case of infection by the side of pharynx; becoming better in two cases of chronic palatitis; very effective in one case of chronic osteomyelitis; becoming better in one case of periostitis; cured in one case of acute bacterial testitis; and ineffective in one case of acute leukemia combined with infection.

Table 2 Blood Density and Half-life Period
After Taking Sulfamethoxinum Orally

Place and Quantity of Dose	Number of Cases	Average Density in Blood (mg/100ml)												Half-life period (hour)	
		1/12	1/6	1/4	1/2	1	3	4	7	8	10	14	21		
Healthy people:															
Shanghai, dose 1.0g.	20	7.4	8.2	7.6	6.6	6.2	5.5	...	4.3	2.1	1.9	1.5	203
Tai-yuan, dose 1.0g.	8	...	7.6	6.3	6.1	...	4.1	...	3.4	190
1.5g.	7	...	9.0	9.0	6.8	6.0	5.7	4.4	228
Sian, dose 1.5g.	3	...	9.5	7.9	...	5.8
Sick people:															...
Nanchang, dose 1.0g.	34	...	7.0	5.3	4.1	212
Sian, dose 1.5g.	32	...	8.8	6.7	...	4.8	182

Note: Figures in the Table 1/12, 1/16 ... represent number of days.

temperature ~~reducing~~ medicine but all produced no result. After entering hospital, he took sulfamethoxinum 1.0g. and injected 10% glucose solution 1,000ml plus vitaminG 1,000mg.. 36 hours later, the subjective and local symptoms completely disappeared.

2. Bacterial Infection of Upper Respiratory Organs and Acute Bronchitis:

After treatment, such symptoms as fever, headache, cough, whole body discomfort and increase of white cells generally come to be under control in a few days. Most cases are cured in 5-7 days. In one case of acute bronchitis, for instance, seven days since the beginning, the patient took 8 ~~ter~~mycin tablets but had no result. After entering the hospital, in

addition to 1.5g. sulfamethoxinum, he took composite liquorice tablets. Three times a day and three tablets once. The next day, his temperature came to normal, and on the sixth day, cough stopped, the lung murmur disappeared and blood condition became normal. On the seventh day, he was cured and released from the hospital.

3. Pneumonia: In the cured cases, the patient's temperature comes to normal in 1-3 days after taking sulfamethoxinum, and in 4-5 days, cough, have spitting and chest pain ^{all} stopped and white cells decreased. By the end of one week, through X-ray examination, the inflammation can be found absorbed. One case of lobaris pneumonia at the middle of right lung, for example, 24 hours after taking 1.5g. of sulfamethoxinum, the patient's temperature came to normal. On the third day, cough and sputum were subdued. On the fourth day, blood condition became normal and on the seventh day, the chest inflammation completely disappeared. He altogether took 2.0g. of sulfamethoxinum.

4. Acute Bacterial Dysentery: Such symptoms as abdomen-pain, diarrhoea, bloody pus defecation and fever will generally stop in 2-5 days after taking sulfamethoxinum. In one case of acute typical bacterial dysentery, for example, the patient took 3 polymycin tablets without any effect. After entering hospital, he took 1.5g. of sulfamethoxinum, and his fever was gone next day. On the fourth day, defecation and blood condition all became normal. On the seventh day, in order to reinforce the treatment, the patient was asked ^{to take} 0.5g. more of sulfamethoxinum. From fifth through eighth days, four consecutive tests of excrement culture were made and all were negative. On the nineth day, he was cured and released from hospital.

When sulfamethoxinum is applied to treat bacterial dysentery, the vanishing of dysenteriae bacillus in excrement is slower than the fading away of the disease. According to the observation of 10 setups of excrement culture in Sian, within 7 days those that turn into negative are 5, and within 14 days are 9. In an individual case treatment, the bacteria in excrement turn from negative to positive, and bloody pus defecation happens again. There are two more serious cases of typical bacterial dysentery. The patients' temperature is $39.2-40^{\circ}\text{C}$, and ~~diarrhea~~ more than 20 times a day. After taking 1.5g. of sulfamethoxinum and through observation for three days, they show no sign of getting better. Then they change to use other medicine and are all cured.

5. Soft Structure Infection: Among the cases of treatment, there are patients who have used several different kinds of antitoxin without any result. After they change to use sulfamethoxinum, the subjective and local symptoms are all getting better. In Nanchang, from the secrete of soft structure pyogenes infection, three sets of culture are made and from the culture aureus staphylococcus are found. As the result of treatment by using sulfamethoxinum, two cases get well, and one does not. So it is evident that this medicine is also effective in treating pyogenes disease on skin and soft structure.

Density of Sulfamethoxinum in Blood

To measure free sulfamethoxinum content in whole blood usually uses the method of coupled nitride colorimetry and the coloration agent is 2-hydrochloric acid N-1-naphthylenediamine. The result can be seen

in Table 2.

From the result of measuring blood density, it can be found out that the half-life period of sulfamethoxinum in human blood is 182-228 hours (7.6-9.5 days), and the average is 203 hours. Four hours after taking the medicine orally, blood density can reach its peak. Those who take a dose of 1.0g. is 7.0-8.2mg%, and a dose of 1.5g. is 8.8-9.5mg%. In some place, the patient is given an initial dose of 1.0g. and continuously given dose of 0.5g. every three days. Thus the patient can maintain blood density at a constant level of 6.3-7.8mg%.

In Sian, some patients are at the same time given test of free blood sulfamethoxinum in whole and blood plasma. The result is that the density of blood plasma is 50% higher than that of whole blood.

A Comparison of Different Ways of Using Sulfamethoxinum

The effectiveness of using sulfamethoxinum in three different ways is shown in Table 3.

Table 3 A Comparison of Effectiveness of Using Sulfamethoxinum in Three Different Ways

Ways of Using Sulfamethoxinum	Number of Cases					Percentage (%)				
	1	2	3	4	5	1	2	3	4	5
Initial dose 1.5g.	137	14	18	8	177	77.4	7.9	10.2	4.5	100.0
Initial dose 1.0g.	89	7	21	21	138	64.5	5.1	15.2	15.2	100.0
Twice a week	44	7	9	14	74	59.5	9.5	12.2	18.9	100.0
Total	270	28	48	43	389	69.4	7.2	12.3	11.1	100.0

Translator's note: 1-cured; 2-very effective; 3-becoming better; 4-ineffective; and 5-total.

From Table 3, it can be seen that of the group of initial dose 1.5g., the cured rate is 77.4% and the effectiveness rate is 95.5%. They are higher than those of the group of initial dose 1.0g., of which the cured rate is 64.5% and the effectiveness rate is 84.8%. In statistic terms, it means that χ^2 value is 6.37 and 10.62 respectively, and they represent the obvious difference and extraordinarily obvious difference. The group of twice a week shows no higher effectiveness than the group of once a week.

Undesirable Reaction

Among the 389 cases, except that one patient had skin eruption, 9 had dizziness, 4 had light nausea, vomiting, stomach discomfort and stomach pain, no other undesirable reaction was found. In both Sian and Nanchang, before and after taking sulfamethoxinum, 45 patients were given liver function test (a test of the activeness of transaminase), and 38 patients were given kidney function test (a test of non-protein nitrogen in blood). From both tests, nothing was found abnormal.

Discussion and Conclusion

In four places, of using sulfamethoxinum in the treatment of 389 cases of 21 different kinds of bacterial infectious diseases, the effectiveness rate is 88.9%. Among these cases, the cured rate of acute tonsillitis, upper respiratory organ infection, acute bacterial dysentery and pneumonia is relatively high. The medicine is also quite effective in the treatment of acute bronchitis and skin soft structure infection. In many cases, the patients first took antitoxin without ^aany effect, then changed to use

sulfamethoxinum and were cured. In such cases as pneumonia, it is customarily thought that only antitoxin is effective. Now sulfamethoxinum can produce satisfactory result after taking it orally a few times. The advantages of using this medicine are manyfold: it is easy to take, the quantity required is small and the times of using it are fewer. It is particularly suitable for the common and frequent diseases in farm villages.

According to some reports, the lowest bacteriostatic density of sulfamethoxinum in testing tube against pyogenes streptococcus, dysenteria bacillus and pneumococcus is 16-32 microgram/ml. The result of blood density tests made by our different units is that after taking 1-1.5g. of sulfamethoxinum orally, the peak density is about 7-9mg%. After one week, if it lowers by half, namely 3.5-4.5mg%, the effective density is still a few times above provided that the calculation is made on the basis of the lowest bacteriostatic density outside human body. By the result of our clinic experiment, a dose of 1-1.5g. of sulfamethoxinum taken orally is positively effective to less serious infectious diseases of sensitive bacteria.

In Sian, one hospital tried to test the bacteriostatic density of sulfamethoxinum against colibacillus, paracolibacillus, aureus staphylococcus, dysenteria bacillus and others, altogether 42 different kinds of bacteria, they found that when the medicine density is above 12.5mg%, half of the bacteria can be pressed down. Generally, however, after taking this medicine, the blood density cannot reach this level. It is therefore less effective to cure uropoietic system organ infection and heavy-duty bacterial dysentery. By using this medicine alone it is not easy to control theses diseases successfully, and the diseases may come back again after being cured. We

therefore suggest that in treatment of these kinds of diseases, it would be better to add some other kind of antibacterial medicine. Our clinic experience also shows that this medicine produces no good result in treating chronic bronchitis and the combination of bronchophony and bronchiostasis nor is it definitely effective to cure heart disease combined with lung infection and serious pneumonia. So this medicine is not good for serious infection and stubborn chronic infection.

Based on the results of our blood density tests, it becomes clear that the half-life period of sulfamethoxinum in blood is 7.6-9.5 days after taking 1.0 or 1.5g. of it orally. Among all kinds of sulfa-medicine, sulfamethoxinum is so far the only one that can maintain such a long period of effective blood density. From the materials collected from Shanghai and other places, it has become evident that the absorption of sulfamethoxinum is very fast after taking it orally. The blood density can reach its peak four hours after taking it, but it will lower gradually then. On the third and fourth days, it will be 70-80% of four hours.

From the comparison of the effectiveness of using this medicine in three different ways, it becomes clear that the effectiveness of the group of twice a week is not higher than that of once a week. This means that the effect of this medicine can last one week. The cured rate as well as the effectiveness rate of the group of initial dose 1.5g. is higher than that of 1.0g.. Among the cases, in the treatment of acute bacterial dysentery, pneumonia and acute tonsillitis, it shows obvious effectiveness. The blood

density four hours after taking 1.5g. is higher by about 20% than taking 1.0g.. This is probably the reason of the high cured rate in treatment of using this medicine. The degree of blood density is related to individual weight. One who is heavier has lower degree of blood density, otherwise, the higher degree of blood density. Also from the tested materials, it becomes known that the ~~degree~~⁹ of blood density of female is generally higher than that of male. This is probably related to the fact that male is generally heavier in weight than female. We therefore recommend that the initial dose of sulfamethoxinum should be 1-1.5g.. One who is heavier or has more serious infection should take initial dose of 1.5g., then 0.5g. every 3-7 days.

All the available materials indicate that the poisonousness and sensitive reaction of this medicine are smaller than that of SMP. In our experiments, we found no poisonous effect of this medicine to uropoietic system organs, lung and blood. Only in a few cases, the patients had skin eruption, dizziness and nausea. The history of using this medicine is very short, the records of treatment by using this medicine are not yet many in file. Although the undesirable reaction after using this medicine has been so far only a few, we should pay serious attention hereafter to the possibility of having poisonousness when it is used in treatment. According to one report, when the kidney function of the patient is damaged, the half-life period of this medicine in blood can last 570 hours. If there is any poisonous reaction, it is hardly possible to extract it out of the patient's body, thus it may produce seriously damaging result. So we

must try to prevent any abuse of it. Any one who is sulfa-allergy, whose kidney function has been seriously damaged, and whose white cells have decreased should not take this medicine, nor should any infant.

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